

EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 USA
Manufacturing Site(s):	Boston Scientific Limited Ballybrit Business Park Galway IRELAND Boston Scientific Medical Device (Malaysia) SDN BHD PMT 741, Persiaran Cassia Selatan 1, Taman Perindustrian Batu Kawan, 14110 Bandar Cassia, Pulau Pinang Malaysia
EU Authorized Representative:	Boston Scientific Limited Ballybrit Business Park Galway IRELAND
Product Name:	Mustang™, OVER-THE-WIRE, PTA Balloon Dilatation Catheter See Attachment A- Model Designation List
Design Dossier/Technical File:	Technical File 90559783
Product Classification:	Class IIa, Rule 6 according to Annex IX of the MDD

Notified Body:

DEKRA Certification B.V.

Meander 1051
6825 MJ Arnhem
P.O. Box 5185
6802 ED Arnhem
THE NETHERLANDS

Identification Number: 0344

Certificates	
Certificate Name	Certificate Number
Annex II.3 Full Quality Assurance System	3812454 CE 01
EN ISO 13485:2016	3818536 (DEKRA) MD 670368 (BSI)

All BSC SAP manufactured products are released per Global WI Semi-Automated Active Release, [90391555](#), using Global Form Product Shipment Release Requirements, [90213259](#).

We declare that the products identified above are in conformity with all relevant provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices. This declaration is made under Annex II of this directive. All supporting information is retained under the control of the Legal Manufacturer.

Name: Ann Evans

Title: Director, Quality Assurance

Signature: DocuSigned by:
Ann Evans

28 August 2020

Date

 Signer Name: Ann Evans
Signing Reason: I approve this document
Signing Time: 28 August 2020 | 5:46:04 AM EDT

Name: Jenny Jiang

Title: Director, Regulatory Affairs

Signature: DocuSigned by:
Jenny Jiang

28 August 2020

Date

 Signer Name: Jenny Jiang
Signing Reason: I approve this document
Signing Time: 28 August 2020 | 9:31:48 AM EDT
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Attachment A- Model Designation List

Date of CE Marking: 20 April 2011

Table 1: List of UPN/ GTINs for Original DoC

UPN	GTIN	Device Description
H74939171030240	08714729794639	3 mm x 20mm x 40cm
H74939171030340	08714729795025	3 mm x 30mm x 40cm
H74939171030440	08714729794646	3mm x 40mm x 40cm
H74939171030640	08714729795032	3 mm x 60mm x 40cm
H74939171030840	08714729795049	3 mm x 80mm x 40cm
H74939171031040	08714729795308	3 mm x 100mm x 40cm
H74939171040240	08714729794172	4 mm x 20mm x 40cm
H74939171040340	08714729795063	4 mm x 30mm x 40cm
H74939171040440	08714729794103	4 mm x 40mm x 40cm
H74939171040640	08714729795070	4 mm x 60mm x 40cm
H74939171040840	08714729795087	4 mm x 80mm x 40cm
H74939171041040	08714729795315	4 mm x 100mm x 40cm
H74939171050240	08714729794066	5 mm x 20 mm x 40cm
H74939171050340	08714729795094	5 mm x 30 mm x 40 cm
H74939171050440	08714729793731	5 mm x 40 mm x 40 cm
H74939171050640	08714729795100	5 mm x 60 mm x 40 cm
H74939171050840	08714729795117	5 mm x 80 mm x 40 cm
H74939171051040	08714729795124	5 mm x 100 mm x 40 cm
H74939171051240	08714729794882	5 mm x 120 mm x 40 cm
H74939171060240	08714729793908	6 mm x 20 mm x 40 cm
H74939171060340	08714729795131	6 mm x 30 mm x 40 cm
H74939171060440	08714729793564	6 mm x 40 mm x 40 cm
H74939171060640	08714729794783	6 mm x 60 mm x 40 cm
H74939171060840	08714729795148	6 mm x 80 mm x 40 cm
H74939171061040	08714729794899	6 mm x 100 mm x 40 cm
H74939171061240	08714729794905	6 mm x 120 mm x 40 cm
H74939171070240	08714729794370	7 mm x 20 mm x 40 cm
H74939171070340	08714729795155	7 mm x 30 mm x 40 cm
H74939171070440	08714729793588	7 mm x 40 mm x 40 cm
H74939171070640	08714729794790	7 mm x 60 mm x 40 cm
H74939171070840	08714729794806	7 mm x 80 mm x 40 cm
H74939171071040	08714729794813	7 mm x 100 mm x 40 cm
H74939171080240	08714729794660	8 mm x 20 mm x 40 cm
H74939171080340	08714729794400	8 mm x 30 mm x 40 cm

UPN	GTIN	Device Description
H74939171080440	08714729793632	8 mm x 40 mm x 40 cm
H74939171080640	08714729794820	8 mm x 60 mm x 40 cm
H74939171080840	08714729794837	8 mm x 80 mm x 40 cm
H74939171081040	08714729794844	8 mm x 100 mm x 40 cm
H74939171090240	08714729794912	9 mm x 20 mm x 40 cm
H74939171090340	08714729795179	9 mm x 30 mm x 40 cm
H74939171090440	08714729794622	9 mm x 40 mm x 40 cm
H74939171090640	08714729795193	9 mm x 60 mm x 40 cm
H74939171090840	08714729795216	9 mm x 80 mm x 40 cm
H74939171100240	08714729795322	10 mm x 20 mm x 40 cm
H74939171100340	08714729795339	10 mm x 30 mm x 40 cm
H74939171100440	08714729794226	10 mm x 40 mm x 40 cm
H74939171100640	08714729795247	10 mm x 60 mm x 40 cm
H74939171100840	08714729794721	10 mm x 80 mm x 40 cm
H74939171120240	08714729794929	12 mm x 20 mm x 40 cm
H74939171120340	08714729795346	12 mm x 30 mm x 40 cm
H74939171120440	08714729794592	12 mm x 40 mm x 40 cm
H74939171120640	08714729795278	12 mm x 60 mm x 40 cm
H74939171120840	08714729795292	12 mm x 80 mm x 40 cm
H74939171030270	08714729793991	3 mm x 20 mm x 75 cm
H74939171030370	08714729794981	3 mm x 30 mm x 75 cm
H74939171030470	08714729793946	3mm x 40 mm x 75 cm
H74939171030670	08714729794943	3 mm x 60 mm x 75 cm
H74939171030870	08714729794950	3 mm x 80 mm x 75 cm
H74939171031070	08714729794967	3 mm x 100 mm x 75 cm
H74939171031270	08714729794554	3 mm x 120 mm x 75 cm
H74939171031570	08714729794561	3 mm x 150 mm x 75 cm
H74939171031870	08714729794547	3 mm x 180 mm x 75 cm
H74939171032070	08714729794530	3 mm x 200 mm x 75 cm
H74939171040270	08714729793496	4 mm x 20 mm x 75 cm
H74939171040370	08714729794752	4 mm x 30 mm x 75 cm
H74939171040470	08714729793403	4 mm x 40 mm x 75 cm
H74939171040670	08714729794349	4 mm x 60 mm x 75 cm
H74939171040870	08714729794363	4 mm x 80 mm x 75 cm
H74939171041070	08714729794240	4 mm x 100 mm x 75 cm
H74939171041270	08714729794158	4 mm x 120 mm x 75 cm
H74939171041570	08714729794462	4 mm x 150 mm x 75 cm
H74939171041870	08714729794479	4 mm x 180 mm x 75 cm
H74939171042070	08714729794455	4 mm x 200 mm x 75 cm
H74939171050270	08714729793427	5 mm x 20 mm x 75 cm

UPN	GTIN	Device Description
H74939171050370	08714729794707	5 mm x 30 mm x 75 cm
H74939171050470	08714729793366	5 mm x 40 mm x 75 cm
H74939171050670	08714729793977	5 mm x 60 mm x 75 cm
H74939171050870	08714729793960	5 mm x 80 mm x 75 cm
H74939171051070	08714729793892	5 mm x 100 mm x 75 cm
H74939171051270	08714729793915	5 mm x 120 mm x 75 cm
H74939171051570	08714729794042	5 mm x 150 mm x 75 cm
H74939171051870	08714729794486	5 mm x 180 mm x 75 cm
H74939171052070	08714729794202	5 mm x 200 mm x 75 cm
H74939171060270	08714729793397	6 mm x 20 mm x 75 cm
H74939171060370	08714729794318	6 mm x 30 mm x 75 cm
H74939171060470	08714729793335	6 mm x 40 mm x 75 cm
H74939171060670	08714729793762	6 mm x 60 mm x 75 cm
H74939171060870	08714729793854	6 mm x 80 mm x 75 cm
H74939171061070	08714729793625	6 mm x 100 mm x 75 cm
H74939171061270	08714729794127	6 mm x 120 mm x 75 cm
H74939171061570	08714729793984	6 mm x 150 mm x 75 cm
H74939171061870	08714729794493	6 mm x 180 mm x 75 cm
H74939171062070	08714729794509	6 mm x 200 mm x 75 cm
H74939171070270	08714729793502	7 mm x 20 mm x 75 cm
H74939171070370	08714729794271	7 mm x 30 mm x 75 cm
H74939171070470	08714729793342	7 mm x 40 mm x 75 cm
H74939171070670	08714729793861	7 mm x 60 mm x 75 cm
H74939171070870	08714729794264	7 mm x 80 mm x 75 cm
H74939171071070	08714729793779	7 mm x 100 mm x 75 cm
H74939171071270	08714729794424	7 mm x 120 mm x 75 cm
H74939171071570	08714729794578	7 mm x 150 mm x 75 cm
H74939171071870	08714729794608	7 mm x 180 mm x 75 cm
H74939171072070	08714729794189	7 mm x 200 mm x 75 cm
H74939171080270	08714729793519	8 mm x 20 mm x 75 cm
H74939171080370	08714729793809	8 mm x 30 mm x 75 cm
H74939171080470	08714729793328	8 mm x 40 mm x 75 cm
H74939171080670	08714729793885	8 mm x 60 mm x 75 cm
H74939171080870	08714729793656	8 mm x 80 mm x 75 cm
H74939171081070	08714729793700	8 mm x 100 mm x 75 cm
H74939171081270	08714729794431	8 mm x 120 mm x 75 cm
H74939171081570	08714729794585	8 mm x 150 mm x 75 cm
H74939171081870	08714729794615	8 mm x 180 mm x 75 cm
H74939171082070	08714729794196	8 mm x 200 mm x 75 cm
H74939171090270	08714729793755	9 mm x 20 mm x 75 cm

UPN	GTIN	Device Description
H74939171090370	08714729794851	9 mm x 30 mm x 75 cm
H74939171090470	08714729793489	9 mm x 40 mm x 75 cm
H74939171090670	08714729794691	9 mm x 60 mm x 75 cm
H74939171090870	08714729794868	9 mm x 80 mm x 75 cm
H74939171100270	08714729793601	10 mm x 20 mm x 75 cm
H74939171100370	08714729794394	10 mm x 30 mm x 75 cm
H74939171100470	08714729793359	10 mm x 40 mm x 75 cm
H74939171100670	08714729794004	10 mm x 60 mm x 75 cm
H74939171100870	08714729794332	10 mm x 80 mm x 75 cm
H74939171120270	08714729793922	12 mm x 20 mm x 75 cm
H74939171120370	08714729794875	12 mm x 30 mm x 75 cm
H74939171120470	08714729793441	12 mm x 40 mm x 75 cm
H74939171120670	08714729794738	12 mm x 60 mm x 75 cm
H74939171120870	08714729794745	12 mm x 80 mm x 75 cm
H74939171030210	08714729794141	3 mm x 20 mm x 135 cm
H74939171030310	08714729794974	3 mm x 30 mm x 135 cm
H74939171030410	08714729794035	3mm x 40 mm x 135 cm
H74939171030610	08714729794998	3 mm x 60 mm x 135 cm
H74939171030810	08714729794936	3 mm x 80 mm x 135 cm
H74939171031010	08714729794295	3 mm x 100 mm x 135 cm
H74939171031210	08714729793816	3 mm x 120 mm x 135 cm
H74939171031510	08714729794516	3 mm x 150 mm x 135 cm
H74939171031810	08714729794523	3 mm x 180 mm x 135 cm
H74939171032010	08714729794387	3 mm x 200 mm x 135 cm
H74939171040210	08714729793724	4 mm x 20 mm x 135 cm
H74939171040310	08714729795056	4 mm x 30 mm x 135 cm
H74939171040410	08714729793557	4 mm x 40 mm x 135 cm
H74939171040610	08714729794257	4 mm x 60 mm x 135 cm
H74939171040810	08714729794028	4 mm x 80 mm x 135 cm
H74939171041010	08714729793717	4 mm x 100 mm x 135 cm
H74939171041210	08714729793670	4 mm x 120 mm x 135 cm
H74939171041510	08714729793694	4 mm x 150 mm x 135 cm
H74939171041810	08714729794653	4 mm x 180 mm x 135 cm
H74939171042010	08714729793595	4 mm x 200 mm x 135 cm
H74939171050210	08714729793618	5 mm x 20 mm x 135 cm
H74939171050310	08714729794769	5 mm x 30 mm x 135 cm
H74939171050410	08714729793465	5 mm x 40 mm x 135 cm
H74939171050610	08714729793878	5 mm x 60 mm x 135 cm
H74939171050810	08714729793687	5 mm x 80 mm x 135 cm
H74939171051010	08714729793533	5 mm x 100 mm x 135 cm

UPN	GTIN	Device Description
H74939171051210	08714729793410	5 mm x 120 mm x 135 cm
H74939171051510	08714729793434	5 mm x 150 mm x 135 cm
H74939171051810	08714729794219	5 mm x 180 mm x 135 cm
H74939171052010	08714729793373	5 mm x 200 mm x 135 cm
H74939171060210	08714729793571	6 mm x 20 mm x 135 cm
H74939171060310	08714729794776	6 mm x 30 mm x 135 cm
H74939171060410	08714729793472	6 mm x 40 mm x 135 cm
H74939171060610	08714729793939	6 mm x 60 mm x 135 cm
H74939171060810	08714729793793	6 mm x 80 mm x 135 cm
H74939171061010	08714729793540	6 mm x 100 mm x 135 cm
H74939171061210	08714729793526	6 mm x 120 mm x 135 cm
H74939171061510	08714729793458	6 mm x 150 mm x 135 cm
H74939171061810	08714729794059	6 mm x 180 mm x 135 cm
H74939171062010	08714729793380	6 mm x 200 mm x 135 cm
H74939171070210	08714729793830	7 mm x 20 mm x 135 cm
H74939171070310	08714729795001	7 mm x 30 mm x 135 cm
H74939171070410	08714729793649	7 mm x 40 mm x 135 cm
H74939171070610	08714729794325	7 mm x 60 mm x 135 cm
H74939171070810	08714729794288	7 mm x 80 mm x 135 cm
H74939171071010	08714729794011	7 mm x 100 mm x 135 cm
H74939171071210	08714729794097	7 mm x 120 mm x 135 cm
H74939171071510	08714729793786	7 mm x 150 mm x 135 cm
H74939171071810	08714729794677	7 mm x 180 mm x 135 cm
H74939171072010	08714729793748	7 mm x 200 mm x 135 cm
H74939171080210	08714729793847	8 mm x 20 mm x 135 cm
H74939171080310	08714729794417	8 mm x 30 mm x 135 cm
H74939171080410	08714729793663	8 mm x 40 mm x 135 cm
H74939171080610	08714729794714	8 mm x 60 mm x 135 cm
H74939171080810	08714729794301	8 mm x 80 mm x 135 cm
H74939171081010	08714729794233	8 mm x 100 mm x 135 cm
H74939171081210	08714729794448	8 mm x 120 mm x 135 cm
H74939171081510	08714729794110	8 mm x 150 mm x 135 cm
H74939171081810	08714729794684	8 mm x 180 mm x 135 cm
H74939171082010	08714729794080	8 mm x 200 mm x 135 cm
H74939171090210	08714729794165	9 mm x 20 mm x 135 cm
H74939171090310	08714729795162	9 mm x 30 mm x 135 cm
H74939171090410	08714729794134	9 mm x 40 mm x 135 cm
H74939171090610	08714729795186	9 mm x 60 mm x 135 cm
H74939171090810	08714729795209	9 mm x 80 mm x 135 cm
H74939171100210	08714729794073	10 mm x 20 mm x 135 cm

UPN	GTIN	Device Description
H74939171100310	08714729795223	10 mm x 30 mm x 135 cm
H74939171100410	08714729793823	10 mm x 40 mm x 135 cm
H74939171100610	08714729795230	10 mm x 60 mm x 135 cm
H74939171100810	08714729795254	10 mm x 80 mm x 135 cm
H74939171120210	08714729794356	12 mm x 20 mm x 135 cm
H74939171120310	08714729795261	12 mm x 30 mm x 135 cm
H74939171120410	08714729793953	12 mm x 40 mm x 135 cm
H74939171120610	08714729795018	12 mm x 60 mm x 135 cm
H74939171120810	08714729795285	12 mm x 80 mm x 135 cm